

Standard Operating Procedures For FDA Reorganizations



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OFFICE OF OPERATIONS
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MANAGEMENT ANALYSIS SERVICES STAFF

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Standard Operating Procedure For Reorganizations

Purpose:

The purpose of this document is to supplement the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) policies and guidelines on preparing reorganization packages. The intent of this Standard Operating Procedure (SOP) is to provide clarifying information on the reorganization process that governs the preliminary planning process (development), review/clearance process (evaluation, coordination, reprogramming procedures, review and approval), and post approval and implementation process of all reorganizations for FDA.

Guidelines:

1. HHS General Administration Manual 8-60, Reorganization Procedures and Guidance;
2. HHS General Administrative Manual 8-100, Delegations of Authority and Guidance;
3. Staff Manual Guide 1005.1, Organizational Changes – Policy and Procedures; and
4. Staff Manual Guide 1415.5, Authority to Approve Organization Structure and Functional Statements.

Preliminary Planning Process:

The Center/Office Liaison will schedule a preliminary planning meeting with the Management Analysis Services Staff (MASS) to determine if a reorganization is required. The preliminary planning meeting should include representation for the following to provide input and recommendations:

- OHR/MASS
- Center/Office Liaison
- Office of Human Resources (OHR)
 - Client Services Division's (CSD) respective Branch Chief or Designee (BC/Designee)
 - OHR Workforce Relations Division's (WRD) respective Branch Chief or Designee (BC/Designee)
- Office of Finance, Budget, and Acquisitions/Office of Budget (OB)
 - Budget Execution Staff (BES)
 - OB Budget Formulation Staff (BFS)

The following steps outline the requirements and rules for each Office in the preliminary planning process:

Step 1. (Center/Office Liaison): Prepare the following draft documents and schedule the preliminary planning meeting:

1. Executive Summary
2. Budgetary Tables
3. Current Organizational Charts
4. Proposed Organizational Charts
5. Staffing Crosswalk

Step 2. (Center/Office Liaison): The preliminary planning meeting discussions will include the major issues/concerns and with the following organizations:

OFBA BES & BFS: These two organizations will review all required documents within a reorganization package with regard to the financial part of the program activities for compliance with financial management policies and regulations; potential changes to any of the financial systems; and to determine if there is a need to notify Congress, Health and Human Services (HHS), and Office of Management and Budget (OMB) with any statutory requirements and/or reprogramming of funds. The following criteria will be used when making this determination:

1. An organization with an Office operating a program, project, or activity that identifies and accompanies an Appropriation Act for reprogramming funds to reorganize Offices in excess of \$500,000 or 10%, whichever is less. Appropriations Committee requires 15 days advance notice; however, all reprogramming requests must be submitted to OB no later than May 15 in order to meet a July 1 Congressional deadline.
2. An organization created by statute or with legislative mandates requires a Congressional Notification without regard to the funding identified in Step 2, #1.
3. An organization that has been the subject of recent attention by the Appropriations Committees or has received recent adverse attention in the media. ("Recent" refers to two years or less).

Center/Office Liaison and OHR/CSD (jointly): OHR/CSD is the primary organization for all human capital resources and position management for the Agency, and assures that any changes via a reorganization or any individual action is in compliance with Agency; Department; and Office of Personnel Management policy and regulations. Therefore, the Center/Office Liaison may need to reach out to CSD Branch Chief (BC)/Designee for additional discussions/meetings after the initial preliminary planning meeting to review the required documents listed above (especially the Staffing Crosswalk document) to follow up and act on items listed below:

1. Identify which positions require establishment, abolishment, or revisions/updates to position descriptions.
2. Discuss probable impact on newly proposed or existing Senior Executive Service (SES), Senior Title 42 Science Managers, Senior Biomedical Research Service (SBRS), and flag Commissioned Corps positions.
3. Discuss potential impact on grade levels, positions, and career ladders.
4. Discuss issues that may affect Bargaining Unit Employees.
5. Discuss with CSD BC/Designee what other options may be explored or available, such as early out, buyouts, downgrades, etc.
6. Discuss procedures and time requirements to update and approve new appointments and to effect changes to positions.
7. Discuss the Union Notification requirements and process.

MASS: This organizational component is responsible for administering the Agency's reorganization program and assuring compliance with the Department's policies and procedures. Tasks involving the preliminary planning stages are listed below:

1. Discuss the appropriate organizational change (e.g., establishment, retitlement, realignment, and/or abolishment).
2. Identify the approving official for the proposed organizational changes (i.e., Secretary of Health and Human Services, Commissioner of Food and Drugs, Directorates, or Center Director) and notify the Center/Office Liaison within 2-business days.
3. Discuss any affected/applicable Delegations of Authority and the necessary changes.
4. Determine if there is a need for a Federal Register (FR) Notice. If the reorganization is deemed to affect the public, industry, academia, legislatively mandated or reprogramming of funds then the Secretary and Congressional approval required and an FR Notice will need to be prepared.

Review/Clearance Process:

Step 1. (Center/Office Liaison):

1. Based on the preliminary planning meetings and subsequent meetings with all required organizations to resolve any issues concerning the reorganization, the Center/Office Liaison will prepare the official reorganization package with all required documentation. In addition, the Center/Office Liaison will begin working with the Component Delegation Control Officer (CDCO). The CDCO will determine the affected DOAs and ensure compliance with the DOA requirements.

The following documents listed below are required within a reorganization package:

- a. Checklist
 - b. Executive Summary
 - c. Requesting/Action Memorandum
 - d. Clearance Record (FDA Form 2306A)
 - e. Budgetary Tables
 - f. Letters Notifying Congress or OMB, if applicable;
 - g. Union Notification Letter
 - h. Functional Statements (current and proposed)
 - i. Organizational Charts (current and proposed)
 - j. Organizational Charts Alternate Text (proposed)
 - k. Staffing Crosswalk
 - l. Draft Federal Register Notice, if applicable
2. Obtains internal clearance signatures from Center/Office Director requesting the reorganization on the Requesting/Action Memorandum and Clearance Record. Submit all applicable documents to MASS, electronically to the following e-mail address OO-Reorganization@fda.hhs.gov and in hard copy. Note: the signature requirements for the Requesting/Action Memorandum are as listed in the table below:

REQUESTING OFFICIAL	APPROVING OFFICIAL
Commissioner of Food and Drugs	Secretary of Health and Human Services
Deputy Commissioners & Chief Scientist	Commissioner of Food and Drugs
Center/Office Directors	Deputy Commissioners & Chief Scientist
Office Director	Center Director

Step 2. Management Analysis Services Staff (MASS):

1. Upon receipt of the hard copy of the reorganization package, MASS will conduct a cursory review within 1 business day to determine all required documents are included. Once this is completed, MASS will acknowledge and send a notification of receipt for the reorganization package via e-mail to the submitting Center/Office Liaison.
2. If any documentation is missing, the entire package will be returned to Center/Office Liaison and must be resubmitted with all required documentation.
3. Reorganization packages will be reviewed within 5-7 business days to ensure compliance with all applicable policies and procedures. If no deficiencies or revisions are necessary, the review/clearance process will be initiated.
4. Reorganization packages will be scanned and sent electronically for clearance approval to Budget Execution Staff (BES), Budget Formulation Staff (BFS) and OHR/Client Services Division (CSD) Branch Chief (BC)/Designee and OHR/Workforce Relations Division (WRD) BC/Designee. Each Office will have 5-7 business days (counted concurrently) to clear/approve the reorganization package. Note: larger reorganization packages will require additional clearance time of 5-10 business days (counted concurrently). **Offices that have not given their concurrence within 5-10 business days, concurrence will be deemed and the package will be submitted through the final approval process.**

Step 3. Office Human Resources (OHR):

1. The WRD BC/Designee, CSD BC/Designee, and OHR Director will have 5-7 business days each (counted concurrently) to clear/approve the reorganization package. Note: larger reorganization packages will require additional clearance time of 5-10 business days (counted concurrently). If additional time is needed of more than 5-10 business days, OHR must request an extension through MASS.

Step 4. Budget Execution Staff (BES), Budget Formulation Staff (BFS):

1. If Congressional notification is required, BES and BFS will coordinate with the Center/Office to finalize the Congressional letter(s), through the appropriate HHS Offices.
2. If Congressional notification is required, then a Congressional Notification and FR Notice must be prepared for the Secretary of Health and Human Service's approval and submitted to Congress. Note: A Congressional

Notification requires a 15-day comment period to expire before any reorganization may be finalized for publication in the FR Notice.

Step 5. Regulations Editorial Section (RES), Office of Policy (OP), Office of Policy and Planning (OPP), Office of the Commissioner (OC):

1. This organizational component is responsible for assuring all FR Notices are formatted correctly, in compliance with Agency policy and procedures, and approved by the appropriate official prior to submission to the Office of the Federal Register for publication.
2. The requirement of a FR Notice is determined during the preliminary planning meeting phase. If determined necessary, the Center/Office will prepare the FR Notice to include in the reorganization package. Note an FR Notice will be required if the organizational change is legislatively mandated or has significant interest from the public.
3. MASS will review and forward the “draft” FR Notice to RES for review during the clearance/review process.
4. Upon final approval of the reorganization, RES will finalize the FR Notice, obtain approval, and arrange for its publication. Note: the actual publication will take approximately two weeks.

Step 6: MASS:

1. Consolidates/verifies that all necessary clearances have been obtained.
2. Finalizes the official clearance record by adding the effective date for the reorganization package.
3. Submits the reorganization package to the authorized approving official for signature via e-mail or inter-office mail.

Step 7: Authorized Approving Official(s):

1. The authorized approving official (i.e., the Secretary of Health and Human Services, Commissioner of Food and Drugs, Deputy Commissioner/Chief Scientist, or Center Director as previously determined), by virtue of his/her signature, is approving the reorganization request, and the effective date is based upon that signature and date.

Note: Although the request for reorganization has been approved, no movement of employees or filling of positions in the new organization can occur until the Standard Administrative Codes (SACs) are keyed into the personnel database.

Post Approval and Implementation Process:

Step 1. MASS:

Upon receipt of the approved reorganization package, will be monitoring the implementation of all approved reorganizations by:

1. Prepare the Notification of Approval (NOA) to assign the Standard Administrative Codes (SACs) for the new organization(s).
2. Finalizes the official Staff Manual Guides (SMGs) by ensuring that the functional statements, organizational charts, and alternate text documents reflect the approval date of the official reorganization package.
3. Verifies that the SACs have been approved and entered into the Capital HR data base and:
 - Forwards the final NOA and all related documents for the reorganization to the Center/Office Liaison, Budget Execution Staff (BES), Budget Formulation Staff (BFS), and Client Services Division (CSD) Ranch Chief (BC)/Designee; and
 - Submits the final SMGs to the Paperwork Reduction Act and Records Management Staff for publication on Agency websites.
4. Monitors the processing of the Staffing Crosswalks, publication of SMGs, and FR Notices (if applicable).
5. Ensures the affected DOAs are approved and published within the required 90-day implementation period.
6. Resolves any system or implementation issues.
7. Provides status reports to the appropriate officials.

Step 2. BES:

Verifies all funding (payroll & operating), establishes the new CAN numbers, re-allocate any reprogramming of funds, if necessary, and notifies the Centers/Office Budget Contact with the new CANs.

Step 3. Center/Office Liaison:

Formally communicate the reorganization approval to employees and outline an implementation schedule. Collaborate with CSD BC/Designee to ensure the following activities are completed within the required 90-day implementation period:

1. Receives the new CANs from the Center/Office Budget Contact;
 2. Processes, update the revised and/or new position descriptions and OF-8s as necessary;
 3. Finalizes the Staffing Crosswalks by updating employees information, new CANs and new SACs, and submit to CSD BC/Designee for processing realignment actions via email and cc MASS; and
 4. Processes all applicable personnel actions associated with the reorganization.
 - Promotion actions do not normally result from reorganizations, with the exception of career ladder promotions; and
 - Higher graded opportunities resulting from a reorganization must be filled through the competitive process. As a result, the Center/Office Liaison will need to coordinate with CSD BC/Designee on vacancy announcements.
- Note:** Should any change to lower grade situations be necessary, these must be discussed and approved prior to the implementation of the reorganization with CSD BC/Designee and MASS. Employees, who are offered change to lower grade positions, have certain rights and entitlements and specific required procedures must be followed prior to the implementation of the reorganization.
5. Ensures all affected employee records are in Capital HR, EASE, ITAS, and Gov Trip have been updated to reflect the new reorganization.
 6. Check Capital HR to verify the accuracy of all actions, initiate any necessary error corrections, and verify corrections have been completed.
 7. As appropriate to the reorganization, all affected Delegations of Authority must be completed within 90 days after the approval date for the reorganization. Prepare all Delegation documents according to procedures prescribed in General Administration Manual Chapter 8-100, "Delegation of Authority" and submit to MASS for review and processing.

Step 4. CSD:

1. Processes the movement of employees to new positions and to new SACs.
2. Verifies the completion of the personnel realignments

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